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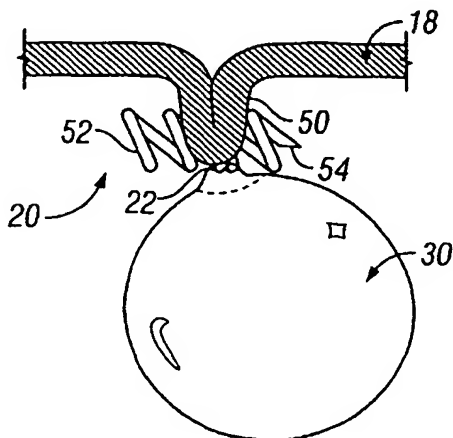
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*For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

(54) Title: INTRA-GASTRIC FASTENING DEVICES



(57) Abstract: Intra-gastric fastening devices are disclosed herein. Expandable devices (30) that are inserted into the stomach of the patient are maintained within by anchoring or otherwise fixing the expandable devices to the stomach walls (18). Such expandable devices, like inflatable balloons (30), have tethering regions (22) for attachment to the one or more fasteners which can be configured to extend at least partially through one or several folds (50) of the patient's stomach wall. The fasteners are thus affixed to the stomach walls by deploying the fasteners and manipulating the tissue walls entirely from the inside of the organ. Such fasteners can be formed in a variety of configurations, e.g., helical (52), elongate, ring, clamp, and they can be configured to be non-piercing. Alternatively, sutures can be used to wrap around or through a tissue fold for tethering the expandable devices. Non-piercing biased clamps can also be used to tether the device within the stomach.

WO 2004/014237 A1

## INTRA-GASTRIC FASTENING DEVICES

### FIELD OF THE INVENTION

[0001] The present invention relates generally to medical apparatus and methods. More particularly, the present invention relates to devices and methods for the attachment of expandable devices and the like within a patient's body cavity, such as the stomach, intestine or gastrointestinal tract.

### BACKGROUND OF THE INVENTION

[0002] In cases of severe obesity, patients may undergo several types of surgery either to tie off or staple portions of the large or small intestine or stomach, and/or to bypass portions of the same to reduce the amount of food desired by the patient, and the amount absorbed by the intestinal tract. Procedures such as laparoscopic banding, where a device is used to "tie off" or constrict a portion of the stomach, or the placement of intragastric balloons can also achieve these results.

[0003] Endoscopic procedures that have been used to assist weight loss have been primarily focused on the placement of a balloon or other space-occupying device in the patient's stomach to fill portions of the stomach to provide the patient with the feeling of fullness, thereby reducing food intake. To accomplish these procedures, an endoscope is utilized to guide the balloon through the patient's mouth and down the esophagus to the stomach. Usually these procedures have allowed placement of the device for 6-12 months, and are coupled with counseling and other types of psychological support.

[0004] Many of the conventional surgical interventions require the patient to submit to an intervention under general anesthesia, and can require large incisions and lengthy recovery time. The less invasive procedures, although clinically efficacious in many cases, suffer from complications ranging from deflation of the devices to insufficient anchoring of these devices resulting in unsustained weight loss, stomach erosion, bowel obstruction and even death.

[0005] Many of these devices are neither robust enough nor are they adequately secured within the stomach to sustain long term implantation. As a result, many implanted devices are implanted in such a manner as to remain unattached or free-floating within the stomach. Further, due to the caustic nature of stomach acids and other factors, many of the

implants deflate and migrate into the intestine, causing bowel obstructions and in some cases death. Also, many devices are not well designed for removal, leading to additional technical difficulties for the clinician.

#### BRIEF SUMMARY OF THE INVENTION

[0006] The present invention provides for the improved methods and apparatus for implanting and anchoring space-occupying devices into the gastrointestinal system of a patient, e.g., the stomach of the patient, that can be deployed in a minimally invasive manner such as transesophageal endoscopy. The invention allows greater access to procedures and devices by patients who might not otherwise be treated surgically as “morbidly obese” (at or above a Body Mass Index (BMI) of 40 kg/m<sup>3</sup>), but who may just be moderately obese or overweight (BMI of between 25 to 40 kg/m<sup>3</sup>). In addition, patients who require more invasive surgery for an unrelated ailment, may need a minimally invasive way to lose the weight prior to their more invasive procedure, thereby reducing the risks associated with general anesthesia, or otherwise enabling the more invasive procedure.

[0007] Expandable devices that may be inserted into the stomach of a patient may be maintained within the stomach by anchoring or otherwise fixing the device to the stomach wall of the patient. Such expandable devices, e.g., an inflatable balloon, may comprise two portions, an inner portion and an outer portion, the inner portion being able to maintain its shape, regardless of the integrity of the outer portion. Other expandable balloon devices which may be used may maintain their expanded shape and desired volume, independent of any small leaks that may develop over time or they may be configured to maintain a volume of the space-occupying device which can be adjusted in-situ, to change the size of the device after implantation.

[0008] The space-occupying devices preferably have a tethering region for attachment to one or more fasteners. The fasteners are configured such that portions of the fasteners may extend at least partially through one or several folds of the patient's stomach wall, thereby maintaining the device within the patient's stomach, but do not extend external to the patient's body. The fasteners may thus be affixed to the stomach walls by deploying the fasteners and manipulating the tissue walls entirely from the inside of the organ.

[0009] Such fasteners may be formed in a variety of configurations, e.g., helical, elongate, ring, clamp, and they may optionally be configured to be non-piercing. For example, sutures may simply be used to wrap around or through a tissue fold for tethering the space-occupying devices. Alternatively, non-piercing biased clamps may also be used to tether the device within the stomach.

#### BRIEF DESCRIPTION OF THE DRAWINGS

[0010] Fig. 1 shows a schematic illustration of a delivery endoscope advanced to a region of interest within the stomach of a patient.

[0011] Fig. 2A shows a cross-sectional view of a stomach within which a tissue fold has been formed from the walls of the stomach.

[0012] Fig. 2B shows the stomach of Fig. 2A in which an inflatable or space-occupying member (in its deflated or unexpanded state) has been advanced for anchoring to the tissue fold.

[0013] Fig. 3 shows the stomach of Fig. 2A and 2B in which the space-occupying member has been expanded for deployment.

[0014] Fig. 4A shows a variation of a helically-shaped fastener which has been positioned within the tissue fold for anchoring the space-occupying member.

[0015] Figs. 4B and 4C show side and end views, respectively, of the fastener of Fig. 4A.

[0016] Fig. 5A shows another variation of an elongate fastener which has been positioned within multiple tissue folds.

[0017] Fig. 5B shows a side view of the fastener of Fig. 5A.

[0018] Fig. 6 shows another variation of a ring-shaped fastener which has been positioned within the tissue fold.

[0019] Fig. 7A shows an end view of another variation of a clamp fastener.

[0020] Fig. 7B shows a side view of the clamp fastener of Fig. 7A.

[0021] Fig. 8 shows another variation in which a piercing or non-piercing suture is used as a fastener for anchoring the space-occupying member to the tissue.

[0022] Fig. 9A shows yet another variation of a clamp fastener.

[0023] Figs. 9B and 9C show cross-sectional side and end views, respectively, of the clamp fastener of Fig. 9A.

## DETAILED DESCRIPTION OF THE INVENTION

[0024] Expandable devices that may be inserted into the stomach of a patient may be maintained within the stomach by anchoring the device to the walls of the stomach using intra-gastric fasteners. Although the fastening devices described herein describe anchoring within a stomach, this is merely illustrative and the fasteners may be utilized in any hollow body organ or interior body space for temporarily or permanently anchoring expandable devices to tissue. Fig. 1 illustrates a delivery endoscope 10 which may be used to deliver the expandable devices as well as the fastening devices into, e.g., stomach 16 of a patient. Endoscope 10 is shown as having been advanced through the mouth 12 and esophagus 14 of the patient to position the distal end of endoscope 10 within a region of interest 20 within stomach 16.

[0025] Fig. 2A shows a cross-sectional view of stomach 16 within which endoscope 10 has been positioned adjacent to region of interest 20. At least one tissue fold 50 is formed from within the lumen of stomach 16 utilizing any number of conventional tools which may be passed through the working channel of endoscope 10, or any of the tissue acquisition devices as described in further detail in U.S. Patent Application Serial No. 09/871,297 filed May 30, 2001 or U.S. Patent Application Serial No. 10/188,547 filed July 2, 2002, both of which are commonly owned and are incorporated herein by reference in their entirety.

[0026] The tissue layers of stomach 16 are comprised of the mucosal layer 32, the muscularis or fibrous muscular layer 34, and the serosal layer 36. In preferably forming tissue fold 50, at least two layers of stomach tissue are folded to contact itself such that a certain amount of fibrous tissue overlap occurs prior to fastening tissue fold 50 in a configuration akin to a lap joint. The amount of the overlap can vary and needs only to be sufficient enough to result in joining of the fastened sections, thereby creating a tissue bridge along the length of the fastened tissue. The tissue bridge may be formed of various layers of the stomach and may include scar tissue and other elements of effective wound healing. Once tissue fold 50 has been desirably configured, a fastener or anchor (as described in further detail below) may be used to maintain the tissue fold configuration for anchoring a space-occupying device thereto.

[0027] Once tissue fold 50 has been formed, the space occupying device, e.g., an expandable scaffold, an inflatable balloon, etc., may be advanced within stomach 16

towards the region of interest 20 for anchoring to tissue fold 50. As shown in Fig. 2B, space-occupying member 30 may be advanced using an elongate delivery member 21, e.g., endoscope 10 or any one of the delivery devices as shown and described in U.S. Patent Application Serial No. 09/816,850 filed March 23, 2001, which is commonly owned and is incorporated herein by reference in its entirety. The use of an inflatable balloon in these examples is intended to be illustrative and any number of space-occupying devices, such as an expandable scaffold, may be utilized as described in the incorporated application. Space-occupying member 30 may have a tethering region 22 integrated on its distal end in the shape of, e.g., a tethering ring or clasp, for attachment to the fastener or anchor which maintains tissue fold 50. During delivery, space-occupying member 30 may be advanced transorally in its deflated state using delivery member 21. Delivery member 21 may also be used to deliver an inert inflation fluid, e.g., water, saline, etc., or an inert gas, e.g., nitrogen, air, etc., through a lumen defined within member 21 for expanding space-occupying member 30 during deployment.

[0028] As seen in Fig. 3, delivery member 21 may be used to inflate space-occupying member 30 into its expanded shape 30'. The surface of space-occupying member 30' may have one or several tabs 40 extending from or defined along its outer surface to allow a grasping tool to manipulate or remove space-occupying member 30' during the procedure or post-procedurally. Space-occupying member 30 may be affixed to tissue fold 50 by attaching tethering region 22 to the fastener or anchor which maintains tissue fold 50. The attachment may be accomplished prior to, during, or even after inflation or expansion of member 30 and may be done by any number of manipulation tools endoscopically or laparoscopically delivered and positioned, as appreciated by one skilled in the art.

[0029] Space-occupying member 30 may be formed of a urethane interior and a silicone exterior. The urethane provides a durability to the balloon for resisting undesirable rupture or leakage and the silicone exterior provides for a smoothness, and conformability to avoid unnecessary trauma or irritation to the stomach lining. In another variation, the member 30 is formed of a composite of silicone, aluminized polyester film, and polyethylene. In this variation, the space occupying device is formed by heat-sealing sheets of mylar/polyethylene composite. The seam is then trimmed to a minimum size and a valve attached. The assembly is then dipped in room temperature vulcanizing (RTV)

liquid silicone which, once cured, will leave a smooth surface, which may or may not have a palpable seam. Alternatively, the space occupying device can be rotated as the silicone cures, to allow for a more consistent coating to form.

**[0030]** A variety of sizes and shapes of space-occupying member 30 are contemplated, and it is to be appreciated that one skilled in the art would be competent to choose a particular shape and size according to the particular application. The space-occupying member 30 can be, for example, a spherical or ellipsoidal balloon or another suitable shape. In the case of an ellipsoidal balloon, one method of anchoring such a balloon is along the longer axis of the balloon; however, anchoring may also be achieved by anchoring along the shorter axis of the balloon. Balloon volumes can vary, but a typical volume is approximately 500 cubic centimeters (cc).

**[0031]** Figs. 4A to 4C show various views of one variation of an anchoring device which may be utilized to maintain the configuration of tissue fold 50 as well as to affix space-occupying member 30 to tissue fold 50. Fig. 4A shows a side view of a helically-shaped fastener 52 pierced through tissue fold 50. Variation 52 is a fastener having a plurality, i.e., more than one, of helical coils 56, as shown in the side view of fastener 52 in Fig. 4B. Fastener 52 preferably has a distal tip 54 which is sharpened to facilitate piercing into and advancement through tissue fold 50 while being rotatably advanced. Fig. 4C shows an end view in which fastener 52 is preferably formed into a circular configuration to provide for smooth advancement and rotation into the tissue, although other shapes such as elliptical are contemplated. It is to fastener 52 that tethering region 22 may be affixed directly or by using a biocompatible connecting member, e.g., a suture.

**[0032]** Fastener 52 is shown as having helical coils 56 at a uniform pitch. However, fastener 52 may be modified such that the pitch of helical coils 56 is non-uniform. In such a variation, the location along coils 56 where the tissue is ultimately compressed may have a pitch which is tighter or higher than the rest of fastener 52. The tighter pitch allows for increased tissue compression along that portion of fastener 52. The remaining helical coils 56 may have a lower or looser pitch to facilitate insertion into the tissue.

**[0033]** Fastener variation 52, as well as other fastening devices described herein, are preferably made of metallic or non-metallic biocompatible materials. Such materials may include stainless steels, nickel alloys, and titanium alloys, as well as biocompatible

plastics. Moreover, any of the fasteners may additionally be coated with a healing agent or anti-bacterial agent to facilitate tissue growth and healing.

[0034] Additionally, the fasteners may have a cutting, abrading, scoring, heating, freezing, chemically damaging, or some other damaging surface where it contacts the tissue. This scoring or roughening may damage the interior lining of the tissue contacting each other. This damage may encourage a more vigorous healing response and a more permanent fixation between the damaged tissue once stapled or affixed together. Detailed examples may be found in U.S. Patent Application Serial No. 09/871,297 filed May 30, 2001, which is commonly owned and is incorporated herein by reference in its entirety.

[0035] Figs. 5A and 5B show another variation of an anchoring device. In this variation, another tissue fold 50' in addition and adjacent to tissue fold 50 may be utilized. Although two tissue folds are shown, any number of folds may be used as practicable depending upon the desired results and anchoring configuration. Fastener variation 60 may include a straight member having rounded ends 62 to facilitate the anchoring placement and positioning within tissue folds 50, 50'. As shown in Fig. 5B, the length of fastener 60 may be textured 64 to improve tissue healing as well as to prevent excessive fastener movement once positioned within the tissue. Space-occupying member 30 may be attached to fastener 60 using tether or connecting member 66, which may be a suture or a rigid connecting pin.

[0036] Another tissue-piercing fastener variation is shown in Fig. 6, which shows a ring-shaped fastener 70 which may pierce tissue fold 50 and connect to tethering region 22 of space-occupying member 30. Ring 70 may be formed as a C-clip type fastener which is biased to remain a closed loop but which may be urged open during deployment. A partial length or the full length of ring 70 surface may be textured, as described above. Moreover, a single ring 70 or several rings may be deployed within the tissue to anchor to the same space-occupying member 30 or to multiple members 30, depending upon the desired results and configuration.

[0037] Yet another variation of the fastener is shown in Figs. 7A and 7B. Fig. 7A shows an end view of clamp fastener 80 which is comprised of two opposed clamp members which are preferably biased towards one another about a hinge portion 82. Fastener 80 may be made of a spring stainless steel or a shape memory alloy, e.g., nickel-titanium alloy, and may be pre-configured into its clamp configuration. As shown in Figs.

7A and 7B, edges 84 may have beads attached around the entire periphery of the clamp or partially thereon either by an adhesive or by forming the beads integrally with the clamp 80. Alternatively, edges 84 may be blunted during manufacturing to provide atraumatic edges for presentation to the tissue surface.

[0038] Clamp 80 may be formed in a variety of shapes, e.g., in a binder clip configuration, a “taco” shell configuration, etc., or any other shape which provides contact surfaces 86 having a contact area sufficient to enable secure anchoring to the tissue. Contact surfaces 86 may be formed with additional anchoring devices such as barbs 88, surface texturing, and/or felt or another tissue in-growth-promoting material. If barbs 88 are used, any number may be used in a variety of barb configurations, e.g., angled barbs, etc.

[0039] To affix space-occupying member 30 to fastener 80, a rotating joint 90 may be used. In this variation, clamp 80 may have attached connector 96 having a balled pivot 94 at a distal end. Tethering region 22 of space-occupying member 30 may have a receiving ring 92 for rotatingly receiving pivot 94. Joint 90 may be utilized on any of the fasteners described herein and allows space-occupying member 30 to rotate freely about the joint without regards to the orientation of clamp 80. This may aid in minimizing tissue tears and excess stress applied to tissue fold 50 as space-occupying member 30 is moved about. To deploy clamp 80, it may be urged into an “open” configuration as it is advanced over tissue fold 50 by the delivery device. Once in position over the tissue, clamp 80 may then be released allowing it to compress upon the tissue to become affixed to tissue fold 50.

[0040] Another fastener variation 100 is shown in Fig. 8. Suture 100 may simply be used to wrap around tissue fold 50. In this variation, suture 100 may be optionally pierced through the tissue or it may simply be wrapped a number of times around tissue fold 50 to affix space-occupying member 30. Suture 100 may be made of any suitable material, e.g., stainless steel, nylon, polypropylene, or any other conventional suturing material.

[0041] Yet another variation is shown in Figs. 9A to 9C of a non-piercing clamp fastener 110. Fastener 110 in this variation is comprised of at least two opposed collar portions 112 which are connected by a biasing connecting member 114. Member 114 is preferably configured to provide a biasing force such that portions 112 are urged towards one another. Collar portions 112 collectively define a receiving channel 116 through which

tissue fold 50 may be positioned and held. Contact walls 118 of receiving channel 116 may be smooth and non-piercing, but they may optionally have a number of teeth or barbs which project into channel 116 for completely or partially penetrating the tissue held therewithin. Moreover, contact walls 118 may have its area varied depending upon the shape and area of the tissue surface presented. For instance, if the tissue area for attachment is formed in the shape of a uvula, then the area of contact walls 118 may be minimized and optionally tapered to receive the bulging contact tissue. If the tissue area is formed more as a fold of tissue, the area of contact walls 118 may be enlarged to present a larger contact region to the tissue, as in the variation of Figs. 7A and 7B.

[0042] With the collar portions 112 clamping onto tissue fold 50, suitable grasping or holding pressure is applied by the fasteners to maintain attachment to tissue fold 50. If too much pressure is applied, the tissue 50 being compressed may necrose, but if too little pressure is applied, slippage of fastener 110 may occur. Accordingly, the suitable amount of pressure may be determined by one of skill in the art depending upon factors such as the size of tissue fold 50 and the size of fastener 110, among other factors.

[0043] Although preferred illustrative variations of the present invention are described above, it will be evident to one skilled in the art that various changes and modifications may be made without departing from the invention. For instance, variations of the present invention may be used as permanent or temporary anchoring devices. Moreover, modified variations may also be used in other regions of the body, e.g., for use in the intestinal tract, etc. It is intended in the following claims to cover all such changes and modifications that fall within the true spirit and scope of the invention.

## CLAIMS

We claim:

1. A method of anchoring an object to a region of tissue within a hollow body organ, comprising:
  - grasping the region of tissue from an interior surface of the hollow body organ;
  - configuring the region of tissue to create at least one fold of tissue; and
  - securing a fastener to the fold of tissue such that the object fixedly depends from the fastener and is affixed to the region of tissue within the hollow body organ.
2. The method of claim 1 further comprising advancing an endoscope transorally to the region of tissue.
3. The method of claim 1 wherein the hollow body organ comprises a stomach.
4. The method of claim 1 wherein grasping the region of tissue comprises holding the tissue with a vacuum force.
5. The method of claim 1 wherein grasping the region of tissue comprises holding the tissue mechanically.
6. The method of claim 1 wherein configuring the region of tissue comprises creating at least two adjacent folds of tissue.
7. The method of claim 1 wherein securing the fastener comprises piercing the fold of tissue with the fastener.
8. The method of claim 7 wherein the fastener is pierced through a first surface of the fold to a second surface of the fold.
9. The method of claim 7 wherein the fastener is pierced partially through the fold of tissue.

10. The method of claim 7 wherein piercing the fold of tissue comprises rotating a helically-shaped fastener at least partially through the fold of tissue.

11. The method of claim 7 wherein securing the fastener further comprises mechanically clamping the fastener over the fold of tissue.

12. The method of claim 1 wherein securing the fastener comprises mechanically clamping the fastener over the fold of tissue.

13. The method of claim 1 wherein securing the fastener comprises suturing the object to the fold of tissue.

14. A system for occupying a volume within a lumen of a hollow body organ, comprising:

a space-occupying member having a tethering region; and

a fastener adapted to be secured through at least one fold of tissue created from an interior surface of the hollow body organ,

wherein the tethering region of the space-occupying member is affixed to the fastener within the hollow body organ.

15. The system of claim 14 wherein the space-occupying member is configured to expand to a predetermined diameter.

16. The system of claim 14 wherein the space-occupying member comprises an inflatable balloon.

17. The system of claim 14 wherein the fastener is adapted to pierce into the fold of tissue.

18. The system of claim 17 wherein the fastener comprises a helically-shaped fastener having a tapered distal tip.

19. The system of claim 17 wherein the fastener comprises an elongate member having a blunt distal end and a blunt proximal end.
20. The system of claim 17 wherein the fastener comprises an expandable ring.
21. The system of claim 17 wherein the fastener comprises a suture.
22. The system of claim 14 wherein the fastener comprises a clamp.
23. The system of claim 14 wherein the tethering region comprises a rotatable joint.

1/7

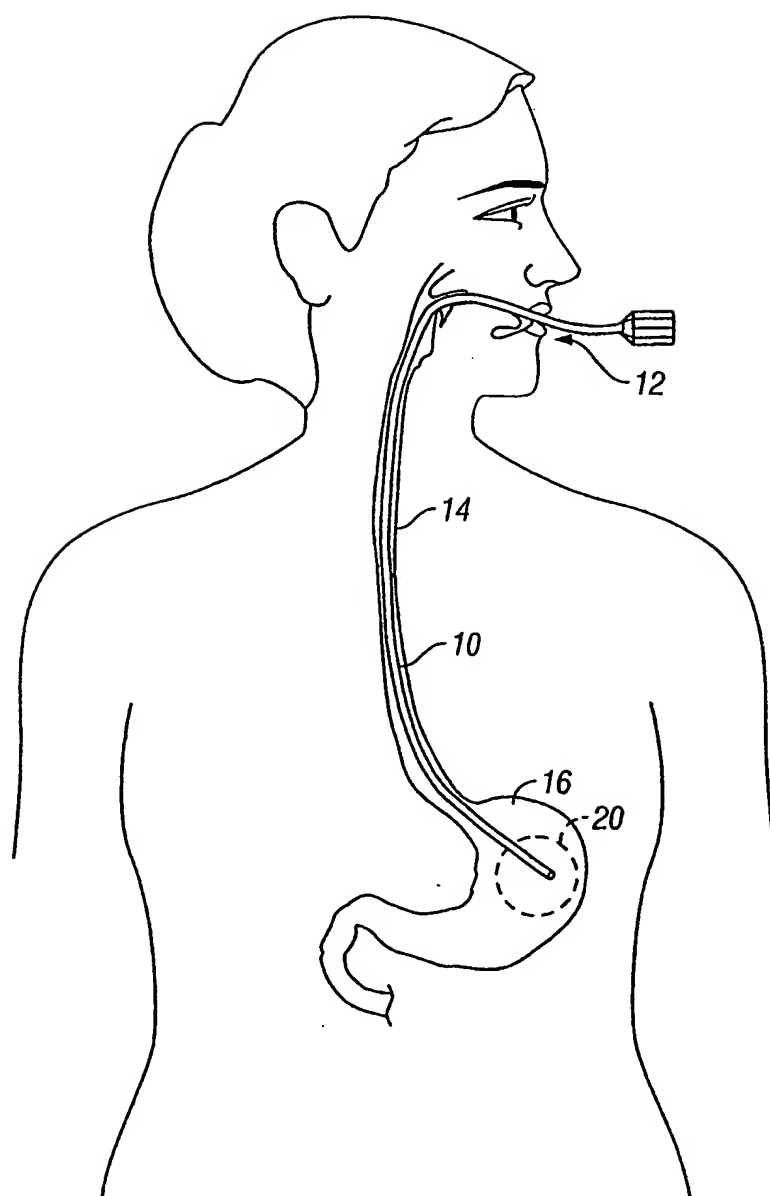


FIG. 1

2/7

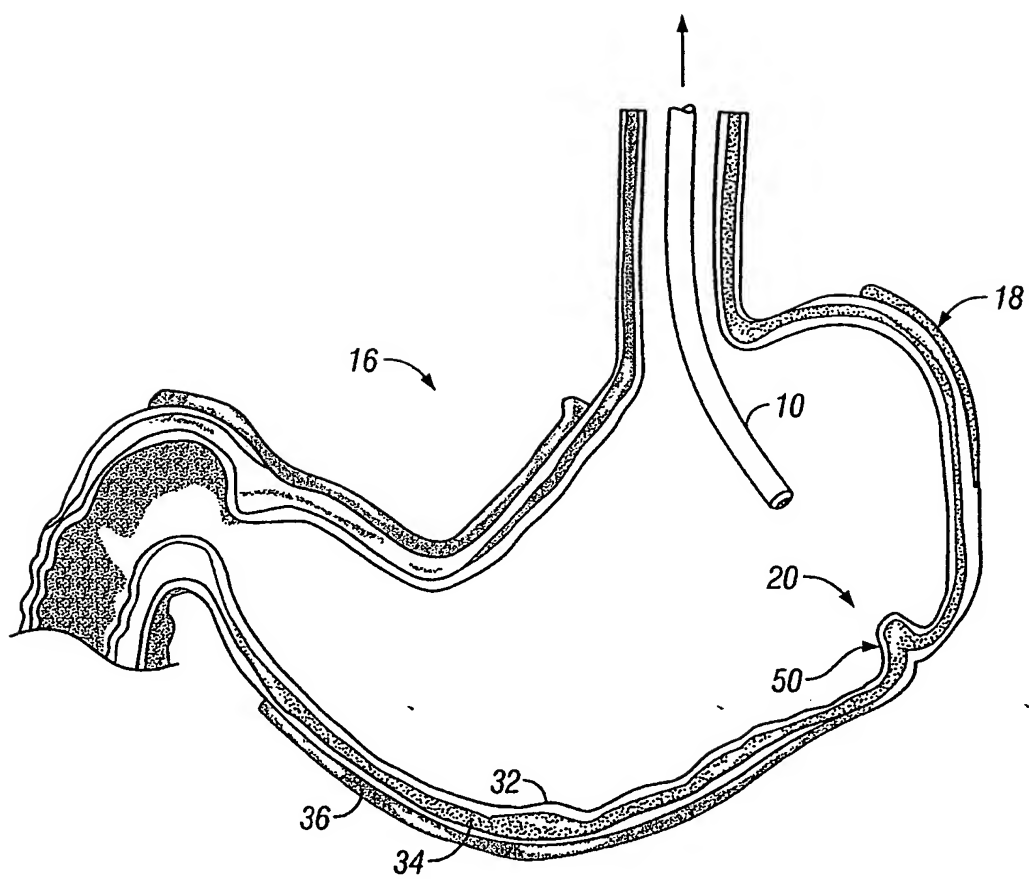


FIG. 2A

3/7

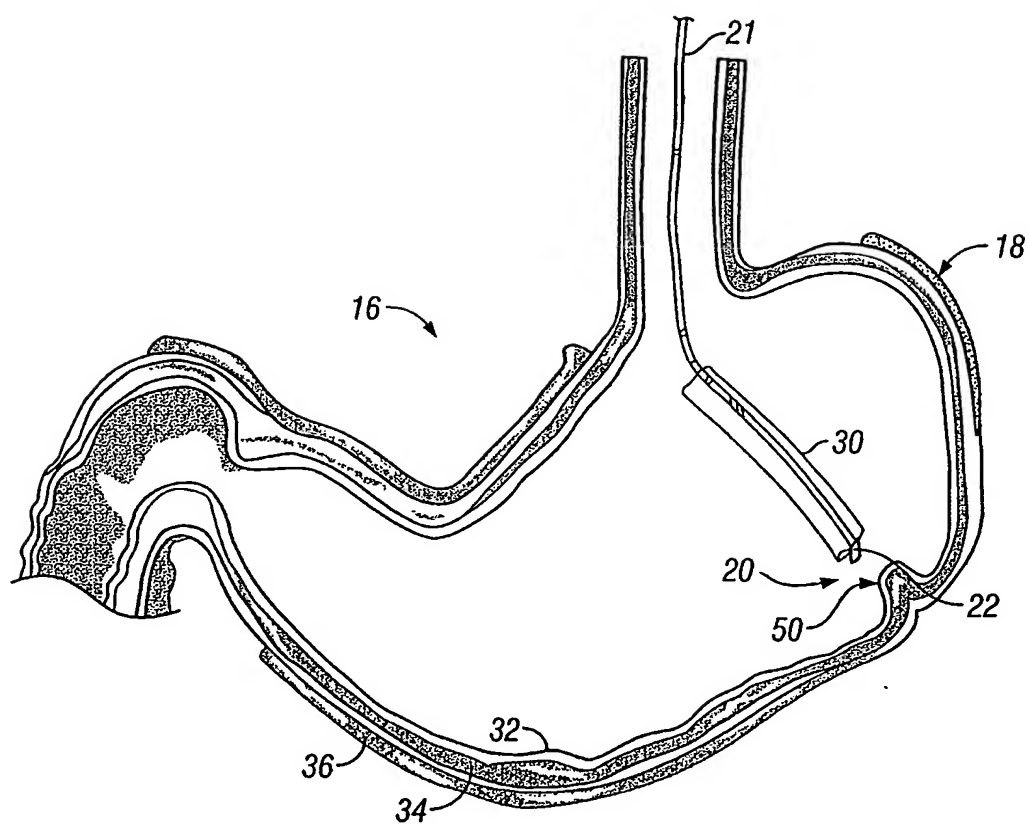


FIG. 2B

4/7

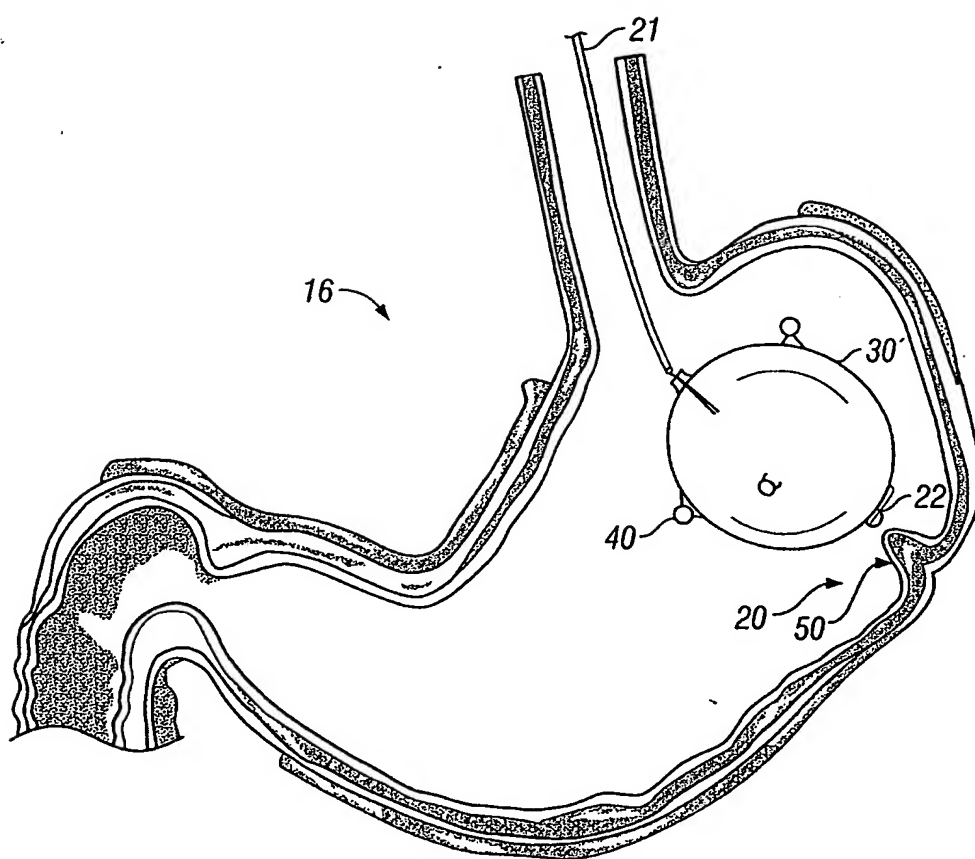


FIG. 3

5/7

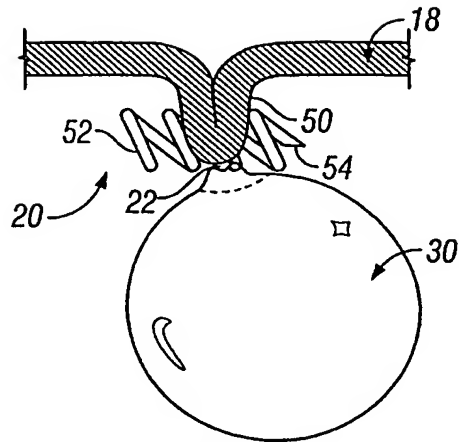


FIG. 4A

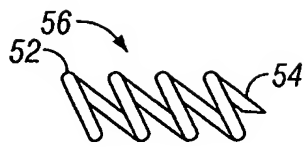


FIG. 4B

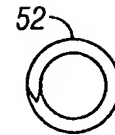


FIG. 4C

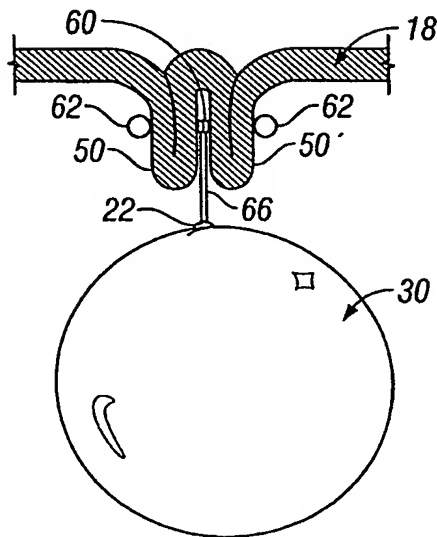


FIG. 5A

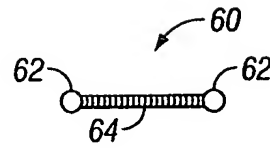
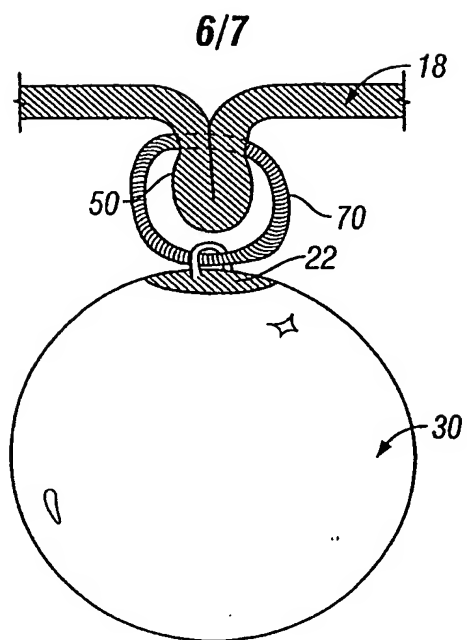
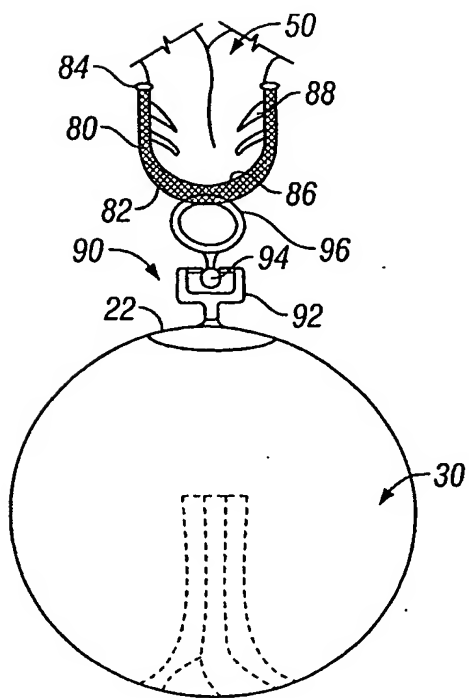


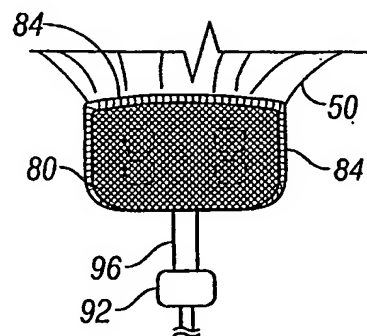
FIG. 5B



**FIG. 6**



**FIG. 7A**



**FIG. 7B**

7/7

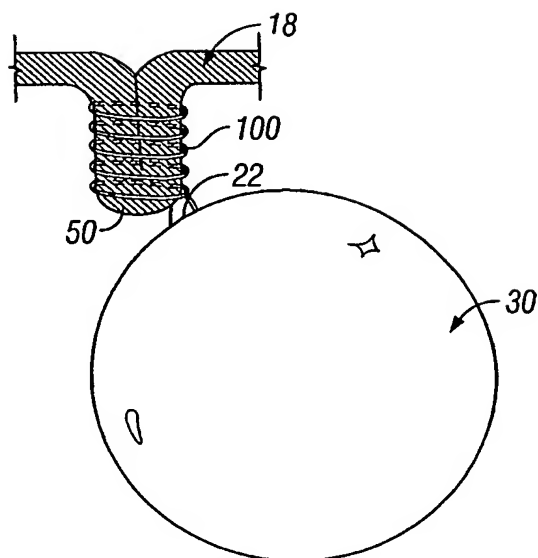


FIG. 8

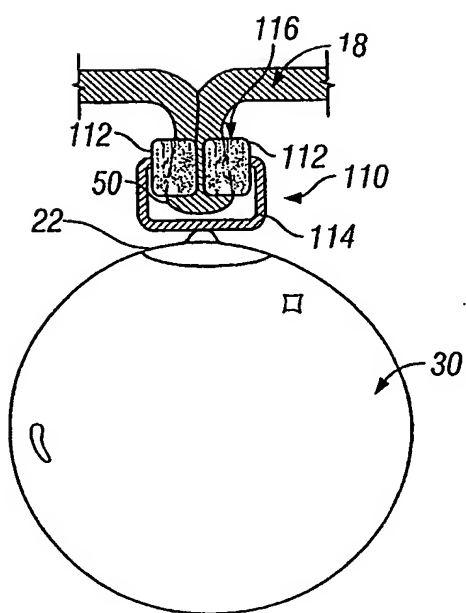


FIG. 9A

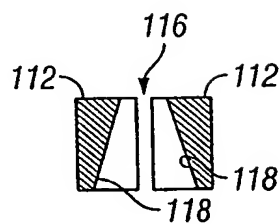


FIG. 9B

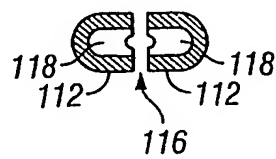


FIG. 9C

# INTERNATIONAL SEARCH REPORT

International application No.

PCT/US03/08853

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61B 17/08

US CL : 606/153, 192, 151

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/153, 192, 151, 155, 156, 213, 232, 219, 220, 195, 216, 221; 623/1.36,23.65

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,037,021 A (Mills et al.) 06 August 1991; Column 1, lines 35-50; Figures 5A-5C.	1-8, 14, 17
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Y		9-13, 15, 18
X	US 5,234,454 A (Bangs) 10 August 1993; Column 5, lines 1-5; Column 5, line 51-Column 6, line 10; Fig. 9.	1
X	US 5,156,609 A (Nakao et al.) 20 October 1992; Column 8, lines 45-55; Column 1, lines 10-30; Fig. 8E.	1-3, 7, 9

☐ Further documents are listed in the continuation of Box C.

☐ See patent family annex.

\* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

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"P" document published prior to the international filing date but later than the priority date claimed

"T"

later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X"

document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y"

document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&"

document member of the same patent family

Date of the actual completion of the international search

11 July 2003 (11.07.2003)

Date of mailing of the international search report

13 AUG 2003

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